REMARKS/ARGUMENTS

After the foregoing Amendment, Claims 3 – 29 and 33 – 37 are currently pending in this application. Claims 1–2 and 30–32 have been canceled without prejudice. Claims 4 – 5, 11 – 17, 23 and 33 – 35 have been amended. Claims 36 – 37 are new. In the Specification, paragraphs [0056] - [0060] have been amended to correct a translation error by changing the word "phytasis" to --phytase--. Applicants submit that no new matter has been introduced into the application by these amendments.

Claim Rejections - 35 USC §112

Claims 1 - 35 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 2 have been cancelled thus rendering the rejection to those claims moot. Claim 17 has been amended to clarify the ranges thus obviating the rejection. Accordingly, withdrawal of the § 112 rejection is respectfully requested.

Claim Rejections - 35 USC §103

Claims 1 – 3, 5 – 6, 8 – 9, 11 – 13, 15 – 26 and 28 – 29 were rejected under 35 U.S.C. §103(a) as obvious over WO 01/83727 to Barendse et al. in view of U.S. Patent No. 4,354,450 to Nagahama et al. Claim 4 was rejected over Barendse in view of Nagahama and further in view of U.S. Patent No. 4,233,007 to Karlsson. Claims 7 and 10 were rejected over Barendse in view of Nagahama and further in view of U.S. Patent No. 4,100,262 to Miller. Claims 14 and 30 – 35 were rejected over Barendse in view of Nagahama and further in view of U.S. Patent Application Publication No. US2006/0105024.

Applicants respectfully traverse the rejection.

Since claim 1 has been cancelled, the comments below deal with new claim 36. New claim 36 contains, *inter alia*, features of claims 1, 2 and 30 – 32.

Barendse describes a method of producing enzyme granules comprising the steps of injecting one or more liquid enzyme preparations via spray nozzles into a fluidized bed subjecting the enzyme solution to a granulation process, separating the particles from the gas flow, returning the particles to the fluidized bed via the gas flow as seed material and discharging the particles via sifters. A disadvantage of the process according to Barendse is that the processing gas is homogeneously distributed over the entire cross section of the fluidized bed.

Consequently there is no concentrated solid comprising gas stream for injection of liquid enzyme formulations, where moistened particles are not only

dried but also granulated as claimed. Dust particles can be returned, but are practically distributed all over the cross section of the fluidized bed. Consequently the formation of granules is slow leading to a long dwell time in the processing space and the granules formed have a suboptimal strength, leading to dust formation. Moreover, the spray of droplets of the enzyme solution and the spray droplets of the inert material are not in close contact. As a result, separate particles of inert material and enzyme particles are formed, instead of particles with a homogeneous matrix as claimed.

The method as claimed provides for producing enzyme granulates, in particular granulates with a low dust content, in which the enzyme granulates can be produced continuously or in separate charges largely avoiding uneven distribution and detrimental effects of temperatures in the production process and in which the yield in conserved activity in the product granules is increased (higher specific activity of the enzyme).

Nagahama shows a method of forming a granulation bed. The disadvantage is that the available space to position the nozzles is very limited. Whereas nozzles in a fluidized bed can be positioned over the entire cross section of the bed, the nozzles in this type of process according to Nagahama must be positioned in a concentrated gas stream only blowing vertically without deflection as is claimed.

Since the number of nozzles is limited, the amount of liquid that can be sprayed into the solid laden gas stream is also limited. As a result, the granulation

capacity of the process in this case is limited, by the amount of liquid material that can be injected in the gas stream, leading to a long dwell time in the processing space. Therefore the capacity of the nozzles has to be optimized.

This problem is aggravated when, in addition to the effective component (in the present case the enzyme), also inert materials must be added in one or more solutions, since an increase in dry matter content will increase the viscosity of liquid and precipitates may be formed that can block the nozzles.

In particular, in the case that salt is added to proteins such as enzymes, the enzyme will precipitate and block the nozzles. It is essential that the intensity of the cold flow of enzyme solution in the pipe leading to the nozzle spraying the enzyme solution is kept above a minimum level, since otherwise the enzyme solution will be heated by the hot air from the processing space and severe activity loss will occur. Moreover, inactivated enzymatic protein will precipitate on the wall and block the supply of liquid, leading to overheating of the whole drying and granulation process.

If no inert material such as a binder is added at all in the granulation process, the strength of the granulates may be inferior, leading to a dusty enzyme granulates.

After extensive experimentation it has surprisingly been found that these problems can be solved and that the capacity of the nozzles can be increased if the inert materials are atomized **separately from the enzyme solution**.

As claimed a process is provided where both the drying and the granulation process is simultaneously carried out within a minimum dwell time of the enzyme material in the processing space, where the temperatures are elevated, without overheating the enzyme material.

This is possible by the process according to claim 36, wherein one or more inert materials are atomized via one or more separate nozzles in addition to the nozzle or nozzles for atomizing the liquid enzyme formulation during the drying and granulation process or parts therefrom and additional protection of the inflowing enzyme solution is given due to the (first horizontal, thus avoiding extensive direct contact with the tubes introducing the enzyme solution, then upwardly directed) flow of the warm processing gas.

As claimed in claim 37, the solutions or suspensions are injected via a three, or a four way nozzle. The advantage is that the limited space in the concentrated solid laden gas stream is used in an optimized way to secure the necessary flow of liquid in order to obtain an optimal speed of agglomeration.

The multiple-way nozzle can be positioned in the center of the chamber whereby the solids in the gas steam will be sufficiently moistened and will agglomerate quickly, and will be dried before they hit the wall of the processing chamber such that they do not stick to the wall but will be recirculated quickly.

The total effect is that the dwell time in the processing space and the contact time with the heated processing gas is reduced such that the enzyme granulates

produced following the method of the invention contain a minimum amount of inactivated enzymes and have a low dust content.

Barendse shows a method for producing enzyme granules comprising the steps of injecting one or more liquid enzyme preparations via spray nozzles into a fluidized bed subjecting the enzyme solution to a granulation process, separating the particles from the gas flow, returning the particles to the fluidized bed via the gas flow as seed material and discharging the particles via sifters. Nothing is mentioned about the problem of long dwell time occurring due to the slow formation of granulates, resulting from the fact that the liquid is not sprayed into a solids-laden gas stream, as claimed, but into a fluidized bed, where the moistened and dry solids are equally distributed in the processing space, and the gas flows more or less homogeneously in one direction in the processing chamber.

Since there is a large amount of space to mount nozzles over the full area of the injection floor provided over the cross-section of the fluidized bed, more low capacity nozzles are required to secure a sufficient flow of liquid into the fluidized bed. Therefore the problem with the limitation of liquid supply as a result of the limited space for nozzles in the area of concentrated gas stream would not exist. Moreover, the hot drying air is well distributed and the hot air flow is not concentrated around the supply pipe of the liquid enzyme solution. The problem of overheating the liquid enzyme solution flowing through the supply pipe does not exist either. Also the liquid spray and moistened particles are spread over the full

cross section of the processing chamber.

However, the moist particles and dried particles are exposed to the same air flow. The result is that dry particles will have a higher temperature than the moist evaporating particles and can overheat. This results in enzyme activity loss, which is aggravated by the fact that the agglomeration between a mixture of dry and moist particles is slower than the agglomeration of moist particles. One of ordinary skill in the art would not find a solution to the problem of reaching a minimum dwell time, since Barendse does not solve the problem of slow formation of agglomerates and the resulting longer dwell time of the permanently fluidized particles. Although Barendse teaches that the drying rate can be increased, this will not reduce the dwell time, since a faster drying rate will not increase the formation of agglomerates, which in the case of a fluid bed is the limiting factor. More undesired fine powder will be formed in a fluidized bed when the drying capacity is increased, and this powder will be recirculated and thus continuously present during the process. Thus the dwell time of the enzyme in the processing space will actually increase. Moreover the nozzles in a fluidized bed are positioned at greater distance from each other. If enzyme solutions and inert materials are sprayed over separate nozzles, inhomogeneous granulates may be formed consisting of mostly inert materials and mostly enzymes, instead of the inert materials being homogeneously integrated in the matrix of the enzyme granulate, leading to low strength granulates.

Nagahama teaches a method of forming a granulation bed where the formation of granulates can be increased if sufficient liquid is injected. However the space for mounting sufficient nozzles is limited and the hot air returned from the processing space flows alongside in direct contact with the liquid supply pipe leading to the nozzle, heating up the liquid solution of the enzyme. This is avoided in the claimed process due to the redirection of the processing gas stream from horizontal to upward. The addition of sufficient liquid active enzyme solution necessary to obtain a quick formation of agglomerates is thus not secured. The supply of sufficient liquid for the formation of agglomerates is a limiting factor in this process.

The Nagahama process may lead to high strength agglomerates. The problem of inactivation of an enzyme, however, as a result to exposure to high temperatures over long dwell times is not addressed, in fact there is no mention of enzymes at all. This is because Nagahama does not relate to processing temperature sensitive materials. Thus one of ordinary skill in the art, even with knowledge of WO01/83727 and U.S. Patent No. 4,354,450, will not search and find a solution to the problem of providing a method that can produce both strong enzyme granulates and then with a minimum of inactivated enzyme material.

It is understood that in the cited prior art, the supply of liquid to be sprayed can be increased by increasing the number of nozzles. In the claimed process the number of nozzles cannot be increased due to a lack of space, since increasing the

space would increase the dwell time.

Without due non-routine and inventive experimentation, with a multiplicity of process variables and various equipment designs, it would not have been obvious that the capacity of the nozzles can be increased by atomizing the enzyme solution separate from the inert materials necessary, in order to obtain an enzyme granulate with a minimum content of inactivated enzymes with the desired composition, thus to provide the desired granulate strength in order to prevent dust formation, that is to be avoided as it can e.g. cause severe allergic problems.

U.S. Patent No. 4,233,007 relates to a type of processes in which a stream of molten metal is disintegrated by directing one or more jets of some suitable atomizing agent. This clearly is not a process agglomerating temperature sensitive material (enzymes), so the problem of inactivation during long dwell time does not exist. Therefore one of ordinary skill in the art of granulating enzymes would not consult '007 to find a solution for their problem, of discharging enzyme granulates via a rotary valve.

In particular, metal particles treated in this reference have a high bulk density, are not sticky and in this case flow straight into one direction downwards into the rotary valve. Thus they have very different properties from the enzyme granulates produced by the claimed method.

U.S. Patent No. 4,009,076 defines a process wherein an enzyme granulate is added in the production of a washing or rinsing medium. However '076 does not

mention anything about the content of inactivated enzymes in the granulate or the roundness.

U.S. Patent Application Publication No. US/0105024 A1 defines a process comprising obtaining a dry enzyme containing granulate and (subsequently) coating the granulate with a dispersion. The process differs from the claimed process in that it is a two step process: The inert (coating) dispersion material is added in a second step. The disadvantage of this process is that the enzyme is subjected to a first heat treatment in a first step to form an enzyme granulate, and a second heat treatment in a second step, where the dispersion is added to coat the enzyme granulate. Therefore the enzyme is exposed to a heat treatment twice in this process and therefore raising the risk of inactivating the enzyme.

There is no mention of adding inert material to be integrated in the matrix of the enzyme granulate, separate from the enzyme solution during the formation of the basic enzyme granulate. Nothing is mentioned about the enzyme activity loss during the granulation process. In addition, nothing is mentioned about the content of inactive enzyme in the granulate or the strength of the granulate.

U.S. Patent Application Publication No. US 2006/0105024 mainly provides information about a coating process for enzyme granulates. Thus, no directing information could have been expected from one of ordinary skill in the art who would not have considered this reference regarding the present invention.

U.S. Patent No. 4,100,263 relates to the recycling of gaseous chlorine in a process of preparing cyanogens chloride. The document does not relate to thermo-sensitive materials and conserving the integrity of these materials – in absolute contrast, the passage alluded to by the Examiner (column 6, first paragraph), lines 3 to 6). relates to the intended decomposition of $Mn(NO_2)_2$ at temperatures not less than 180 °C and thus clearly has no bearing on the present invention – it would not at all be considered by one of ordinary skill in the art.

Based on the amendments and arguments presented above, withdrawal of the § 103 rejection of claims 1 – 35 is respectfully requested.

Conclusion

If the Examiner believes that any additional minor formal matters need to be addressed in order to place this application in condition for allowance, or that a telephone interview will help to materially advance the prosecution of this application, the Examiner is invited to contact the undersigned by telephone at the Examiner's convenience.

In view of the foregoing amendments and remarks, Applicants respectfully submit that the present application, including claims 3 – 29 and 33 – 37, is in condition for allowance and a notice to that effect is respectfully requested.

Respectfully submitted,

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